ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speaker and Panelist

Dr Rainer Gnibl
Government of Upper Bavaria, GMP Inspector

Further Panelists

Dr Sabine Hauck
Leukocare, QP and Chair of ECAs ATMP Interest Group

Dr Andrea Hauser
University Regensburg, Vice Chair of ECAs ATMP Interest Group

Dr Rüdiger Alt
Manager Quality Assurance / Qualified Person ATMP, Novartis

Dr Thomas Meindl
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Stefan Gärtner
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GMP for ATMPs - A Detailed View at the European Guidelines

Streaming of Recorded Presentations from 14-16 June 2021
Live Expert Q&A and Panel Discussion on 17 June 2021

Highlights

- 11 Hours Presentation Time
- 17 Sections / topics of the Guides
- Live Answering of your Questions
- With 6 Experts from Authority, Academia, Industry and Laboratory

- Watch the lectures over 3 days when it suits you.
- Followed by a Live Q&A with an Expert Panel

Background

Relating to the increasing importance of advanced therapy medicinal products (ATMPs) the European Commission and the EMA published a joint document in 2007 with a proposal for a community regulatory framework on ATMPs. With the additional comments of DG enterprise and the industry they issued an implementation plan for the ATMP regulation (Regulation (EC) No 1394/2007) with a date for application on 30 December 2008. In this time, the most ATMPs were in a phase of development and questions about scientific advice, registration and following marketing authorisation were more of interest than GMP issues. But with the increasing number of ATMPs and their development into phases with more GMP relevance, a more detailed guidance on Good Manufacturing Practice for Advanced Therapy Medicinal Products pursuant to Article 5 of Regulation 1394/2007 became essential. Therefore, a first consultation on the development of such a GMP for ATMP guideline was started in July 2015.

Then, on 22 November, the European Commission adopted the "New Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products" which came in operation at 22 May 2018.

The new guideline includes requirements for ATMPs with a marketing authorisation as well as for advanced therapy medicinal products that are being tested or used as reference in a clinical trial (i.e. advanced therapy investigational medicinal products).The document should be the main document for the definition of the GMP requirements for ATMPs, so in the scope it states: *"These Guidelines do not apply to medicinal products other than ATMPs. In turn, the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC4 and Article 63(1) of Regulation (EU) No 536/2014 do not apply to ATMPs, unless specific reference thereto is made in these."*

A look at the over 80 pages and the table of content shows that the status as a stand alone guideline has made it necessary to include all important fields with relation to ATMPs which are normally covered for other medicinal products in the existing GMP guideline and its Annexes.

Target Audience

This seminar is aimed at all persons who are involved in
- development
- marketing authorisation
- manufacturing
- quality assurance
- quality control
- or inspection/auditing

of ATMPs.

Speaker and Panel Discussion Participants

Speaker and Panelist:

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Objectives/Programme

This recorded course and accompanying live panel discussion with regulatory agency speakers and experts from university, small and medium industry, and laboratory will feature 17 lectures that provide both a comprehensive overview of the guidance content.

Your questions will be answered by the experts during the live discussion on 17 June 2021.

The Lectures and approx. time:

	Topic	Length in Minutes
1	EU-GMP for Advanced Therapy Medicinal Products (ATMPs) - an Overview	20
2	Pharmaceutical Quality System	25
3	Quality Risk Management	30
4	Personnel	35
5	Premises & Zone Concept	60
6	Equipment	12
7	Qualification	45
8	Environmental Monitoring	40
9	Materials	59
10	Production	85
11	Validation	60
12	Documentation	45
13	Quality Control	35
14	QP Certification & Batch Release	75
15	Outsourced Activities	20
16	Quality Defects & Product Recalls	20
17	Specific Products & Processes	20

How it works

As a participant you will receive two links, one for streaming the recorded presentations and one for the live Webex Panel Discussion in which your submitted questions will be answered.

- The first link is valid from Monday, 14 June, until Wednesday, 16 June. During these days, you can log in at any time and stream the lectures.
- The second link is for the Panelist Discussion and is valid on Thursday, 17 June, from 14.30 - 16.30 h . You can log in 30 minutes before the start .

Questions to be answered at the live Q&A Session should be send to atmp@gmp-compliance.org.

If the bill-to-address deviates from the specifications on the right, please fill out here:

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GERMANY

Reservation Form (Please complete in full)

GMP for ATMPs - A Detailed View at the European Guidelines
- Streaming of Recorded Presentations, available from 14 to 16 June 2021
- Live Expert Q&A and Panel Discussion on 17 June 2021

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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Streaming of the Recorded Lectures

Available from Monday, 14 June 09.00 h until
Wednesday, 16 June, 24.00 h CEST

Live Q&A/Panel Discussion

Thursday, 17 June 2021, 14.30 – 16.30 h CEST

Technical Requirements

For the Live Online Panel Discussion on 17 June, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
Academic Scientists/ Students € 845
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you in advance as a PDF file. After the event, you will automatically receive your certificate of participation

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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